REMARKS

Claims 21-24 and 28-43 are pending in this application. Claims 21, 28, 30, 31, 32, 34, and 35 have been amended. New Claim 43 has been added. Claims 38-42 have been deemed allowable. Support for the amendments is found in the specification and claims as filed. Attached hereto is a marked-up version of the changes made to the claims by the current amendment. The attached page is captioned "VERSION WITH MARKINGS TO SHOW CHANGES MADE."

Claim Rejections - 35 U.S.C. § 112, first paragraph

Claims 21-24 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. Claim 21 has been amended to recite that "said device measures said glucose accurately for a period of time exceeding 3 weeks ... ." Support for the amendment is found in the specification as filed on page 33, lines 25-28, which state that "[w]hile there are timing variations of the stages from sensor device to sensor device, generally speaking, the first three steps of this process take from 3 days to three weeks and continuous sensing has been observed for periods thereafter", namely, a period of time exceeding three weeks. In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection of Claims 21-24.

Claims 32-37 have been rejected under 35 U.S.C. §112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains to make and/or use the invention. Claim 32 has been amended to recite that "said sensor interface tip communicating with the tissue of said host such that said tip is anchored by tissue ingrowth in said foreign body capsule." Support for the amendment is found in the specification as filed on page 19, lines 16-19, which state that "[s]ome inflammatory response is needed to create a new capillary bed in close proximity to the surface of the sensor in order to i) continuously deliver adequate oxygen and glucose and ii) create sufficient tissue ingrowth to anchor the implant and prevent motion artifact." In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection of Claims 32-37.

Claim Rejections - 35 U.S.C. § 112, second paragraph

Claims 21-24 have been rejected under 35 U.S.C. §112, second paragraph, as being indefinite with regard to the claimed range of the period of time. Claim 21 has been amended to recite that "said device measures said glucose accurately for a period of time exceeding 3 weeks ... ." In view of the foregoing amendment, Applicants respectfully request withdrawal of the rejection of Claims 21-24.

Claim Rejections - 35 U.S.C. § 102(e)

Claims 21-24, 28, 30, and 32 have been rejected under 35 U.S.C. §102(e) as anticipated by U.S. Patent No. 5,704,354 ("Priedel et al."). "A rejection for anticipation under section 102 requires that each and every limitation of the claimed invention be disclosed in a single prior art reference." *See, e.g., In re Paulsen*, 31 U.S.P.Q.2d 1671 (Fed. Cir. 1994). Priedel et al. does not disclose every element of Applicants' claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(e).

Pending independent Claims 21, 28, 30, and 32 recite methods wherein "said device is anchored in said host by tissue ingrowth ... ." Priedel et al. only discloses implantation of a device with a smooth surface that, while evoking a classical foreign body capsule that is in contact with the device, does not permit tissue ingrowth into the device. Thus Priedel et al. does not disclose a device anchored in a host by tissue ingrowth, and therefore cannot anticipate Claims 21-24, 28, 30, and 32. Accordingly, Applicants respectfully request that the anticipation rejections of Claims 21-24, 28, 30, and 32 be withdrawn.

Claim Rejections - 35 U.S.C. § 102(b)

Claims 21-24, 28, 30, 32, and 33 have been rejected under 35 U.S.C. §102(b) as anticipated by U.S. Patent No. 4,721,677 ("Clark Jr."). Clark Jr. does not disclose every element of Applicants' claims, and therefore cannot be considered as an anticipating reference under 35 U.S.C. § 102(b).

As discussed above, pending independent Claims 21, 28, 30, and 32 recite methods wherein "said device is anchored in said host by tissue ingrowth ... ." Clark Jr. discloses an implantable glucose sensor comprising a gas permeable membrane enclosing the sensor. The membrane is described as preferably permeable to small molecules but impermeable to macromolecules, such as protein and the like. See col. 6, lines 43-46. Such a membrane would not permit tissue ingrowth, since it is impermeable to macromolecules, thus Clark Jr. may be

considered to teach away from tissue ingrowth. Accordingly, Clark Jr. not only does not disclose a device anchored in a host by tissue ingrowth, it teaches away from such a device, and therefore cannot anticipate Claims 21-24, 28, 30, 32, and 33. Accordingly, Applicants respectfully request that the anticipation rejections of Claims 21-24, 28, 30, 32, and 33 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

Claim 29 has been rejected under 35 U.S.C. §103(a) as being obvious over Priedel et al. as well as Clark Jr. To articulate a *prima facie* case of obviousness under 35 U.S.C. §103(a), the PTO must, *inter alia*, cite prior art that teaches or suggests all the claimed limitations. *In re Royka*, 490 F.2d 981 (C.C.P.A. 1974). Neither Priedel et al. nor Clark Jr. discloses every element of Applicants' claim, and therefore they cannot be considered references that render obvious Applicants' claim.

Claim 29 is dependent to Claim 28, which recites a method of measuring glucose in a biological fluid "wherein said device is anchored in said host by tissue ingrowth ... ." As discussed above, Priedel et al. and Clark Jr. do not disclose a device anchored in a host by tissue ingrowth. Accordingly, Applicants respectfully request that the obviousness rejection of Claim 29 be withdrawn.

Claim Rejections - 35 U.S.C. § 103(a)

Claim 31 has been rejected under 35 U.S.C. §103(a) as being obvious over Clark Jr. in view of U.S. 5,711,861 ("Ward et al."). Claim 29 is dependent to Claim 28, which recites a method of measuring glucose in a biological fluid "wherein said device is anchored in said host by tissue ingrowth ... ." As discussed above, Clark Jr. does not disclose a device anchored in a host by tissue ingrowth. Ward et al. also does not disclose tissue ingrowth. Accordingly, Applicants respectfully request that the obviousness rejection of Claim 31 be withdrawn.

CONCLUSION

In view of the foregoing amendments and remarks, it is respectfully submitted that the present application is in condition for allowance. Should the Examiner have any remaining concerns which might prevent the prompt allowance of the application, the Examiner is respectfully invited to contact the undersigned at the telephone number below.

Respectfully submitted,

KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: 9/11/02

By: _____

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VERSION WITH MARKINGS TO SHOW CHANGES MADE

Deleted text is indicated by **[bracketed boldface]**. Added text is indicated by **underlined boldface**.

IN THE CLAIMS:

Claims 21, 28, 30, 31, 32, 34, and 35 have been amended as follows:

21. (Twice Amended) A method of monitoring glucose levels, comprising:

a) providing i) a host, and ii) a device comprising a housing and means for determining the amount of glucose in a biological fluid; and

b) implanting said device in said host under conditions such that said device measures said glucose accurately for a period of time exceeding about **three weeks, wherein said device is anchored in said host by tissue ingrowth [about 30 days to exceeding about 360 days]**.

28. (Amended) A method of measuring glucose in a biological fluid, comprising the steps of:

providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing; and

implanting said device subcutaneously**, wherein said device is anchored in said host by tissue ingrowth**.

30. (Amended) A method of measuring glucose in biological fluid, comprising the steps of:

providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing; implanting said device subcutaneously in said host**, wherein said device is anchored in said host by tissue ingrowth,** and transmitting data from said implantable device to an external device.

31. (Twice Amended) A method of measuring glucose in a biological fluid, comprising the steps of: providing i) a host, and ii) an implantable device comprising a sensor capable of continuous glucose sensing; implanting said device wholly subcutaneously in said host, **wherein said device is anchored in said host by tissue ingrowth,** and transmitting data by telemetry from said wholly implantable device to an external device.

32. (Twice Amended) A method of measuring glucose in a biological fluid, comprising the steps of:

a) providing a host;

b) providing an implantable device comprising a sensor capable of continuous glucose sensing, said sensor having an interface tip;

c) implanting said device subcutaneously into tissue of said host so as to elicit a foreign body capsule as a result of the response of said host to the introduction of said implantable device, said sensor interface tip communicating with the tissue of said host such that said tip is **[substantially fixated] anchored by tissue ingrowth** in said foreign body capsule.

34. (Amended) A method according to claim 32, wherein said sensor tip is **[substantially fixated] anchored** in said foreign body capsule by the provision of a capsular attachment layer on said sensor.

35. (Amended) A method according to claim 34, wherein said sensor tip is further **[substantially fixated] anchored** by the provision of an angiogenic layer on said sensor.

New Claim 43 has been added:

43. (New) The method of claim 21, wherein said device measures said glucose accurately for a period exceeding 360 days.